

REMARKS

Claims 1-35 are pending in this application. Claims 1-17 have been withdrawn as being directed to non-elected subject matter.

Independent claim 18 is directed to "[a] sponge for iontophoretic administration of charged drugs to a tissue of a subject, comprising: a porous structure configured and operable to absorb and hold at least 30% w/w aqueous solutions without dissolving or disintegrating, the porous structure comprising a surface area of contact with the tissue; and a data transmitting module configured and operable to transmit data indicative of one or more of sponge size and the surface area of contact of the sponge with the tissue of the subject. Claims 19-35 depend, either directly or indirectly, from claim 18.

No new matter has been added.

In view of the remarks set forth below, further and favorable consideration is respectfully requested.

- I. At page 3 of the Official Action, claims 18-22, 26-29, 31-35 have been rejected under 35 USC § 103(a) as being unpatentable over Jacobsen et al. (US 4,250,878) in view of Sun et al. (US 2002/0115957).***

The Examiner asserts that it would have been obvious to modify the device described by Jacobsen et al. with a data transmitting module capable to transmit data indicative of one or more of sponge size.

In view of the following these rejections are respectfully traversed.

To establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more

than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. 398 at 417.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Regarding motivation to modify properly combined references, **MPEP 2143** states that where the prior art conflicts, all teachings must be considered and that the fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness. **MPEP 2143** further states that there must be some suggestion or motivation to modify the references, and there must be a reasonable expectation of success.

MPEP 2143.01 states that a proposed modification cannot render the prior art unsatisfactory for its intended purpose. If it does, then there is no suggestion or motivation to make the proposed modification. Further, the proposed modification cannot change the principle operation of a reference.

It is submitted that a *prima facie* case of obviousness has not been established because, whether taken alone or together, the cited references do not teach or suggest every element of the claimed subject matter as required by *In re Wilson*. In addition, applicants submit that there is no motivation to modify Jacobsen et al. and Sun et al. to arrive at the present subject matter because doing so would change the principle of operation required by Jacobsen et al. and Sun et al., i.e., indirect contact with the skin of a user.

Claim 18 is directed to a sponge for iontophoretic administration of charged drugs to a tissue of a subject, comprising: ***a porous structure configured and operable to absorb and hold at least 30% w/w aqueous solutions without dissolving or disintegrating, the porous structure comprising a surface area of contact with the tissue***; and a data transmitting module configured and ***operable to transmit data indicative of one or more of sponge size and the surface area of contact of the sponge with the tissue of the subject.***" (Emphasis added). Claims 19-22, 26-29 and 31-34 depend, either directly or indirectly, from claim 18,

In contrast, Jacobsen et al. is directed to a bioelectrode for non-invasive and inotophoretic delivery of chemical species. See Jacobsen et al. at the Abstract. However, it is submitted that unlike the presently claimed subject matter, Jacobsen et al. do not teach or suggest a sponge having surface area of contact with the tissue, a

porous structure which is capable of absorbing and holding at least 30% w/w of an aqueous solution without dissolving or disintegrating or a data transmitting module configured and operable to transmit data indicative of one or more of sponge size and the surface area of contact of the sponge with the tissue of the subject, as recited in claim 18.

With specific regard to the sponge having a surface area of contact with the tissue of a subject, Applicants submit that the bioelectrode described by Jacobson by al. requires a pouch having flexible walls, at least part of which is composed of a microporous, permeable or semipermeable membrane. However, the pouch described by Jacobsen et al. is always between the porous material and the tissue of a user. As discussed on page 5, lines 19-21 of Jacobsen et al. indicate that "[s]urrounding and enclosing both the rod **84** and the material **86 [i.e., the sponge like material]** is a pouch **82**." Accordingly, Applicants submit that the "sponge" allegedly described by Jacobsen et al. is ***always*** surrounded by an exterior wall, referred to as the pouch. Since the sponge element is completely surrounded by the pouch, the sponge described is not capable of having direct contact with a tissue. To the contrary, according to Jacobson et al., the skin is contacted with the exterior wall or pouch of the electrode and not with the sponge itself. Accordingly, Jacobsen et al. do not teach or suggest every element of the presently claimed subject matter.

Sun et al. do not remedy the deficiencies of Jacobsen et al. Like Jacobsen et al., Sun do not teach or suggest a sponge having surface area of contact with the tissue, a porous structure which is capable of absorbing and holding at least 30% w/w of an aqueous solution without dissolving or disintegrating or a data transmitting module

configured and operable to transmit data signal indicative of one or more of sponge size or surface area of contact of the sponge with a tissue of the subject.

More specifically, Sun et al. is directed to an apparatus for transporting a compound through a barrier membrane of a mammal. The apparatus according to Sun et al. require: a vessel having a membrane contacting surface, ***the surface having a plurality of exposed blades and a channel adjacent to said blades***; a reservoir in communication with said channels for storage of said compound; and an electrode in communication with said reservoir, wherein the width of said blades are tapered away from said surface. See Sun et al. at the abstract.

With regard to describing a sponge having surface area of contact with the tissue, according to Sun et al., the vessel comprises a membrane contacting surface ***which contains a plurality of exposed blades***. Therefore, the blades are in contact with the tissue; however, the “sponge-like” material is not, in any configuration, configured to come into contact with a tissue. See Sun et al. at Figures 7, 8A-D and 9. Applicants note that the structure of the device in which contact with the tissue is affected by rigid blade structure and not by a sponge of any kind.

Sun et al. also do not teach or suggest that the “fluid carrier” does not dissolve or disintegrate, as claimed. Further, Applicants submit that Sun et al. do not teach that the “fluid carrier” has at least 30% w/w of an aqueous solution. While a sponge according to the presently claimed subject matter must not dissolve or disintegrate in order to operate, the fluid carrier of Sun et al. does not provide this structural feature as it is maintained in an internal reservoir or chamber.

With regard to the data transmitting module, Applicants submit that the blades required by Sun et al. are in contact with the tissue; therefore, the electronic element described by Sun et al. (in any of its configurations) cannot describe a data transmitting module "...configured and operable to transmit data signal indicative of one or more of sponge size or surface area of contact of the sponge with the tissue of the subject," as recited in claim 18.

Furthermore, Applicants submit that the structure of the device shown in Fig 7, 8A-D and 9 of Sun et al. require a plurality of exposed blades/channels that do not have varying size or surface area with the tissue. In this regard, Applicants submit that according to Sun et al., there is no varying parameter of size or surface area with the tissue. Therefore, Sun et al. do not teach "... indicative of the sponge's size or surface area...", as recited in claim 18.

In view of the foregoing, Applicants respectfully submit that whether taken alone or in combination, Jacobsen et al. and Sun et al. do not teach or suggest a porous structure configured and operable to absorb and hold at least 30% w/w aqueous solutions without dissolving or disintegrating, the porous structure comprising a surface area of contact with the tissue, or a data transmitting module configured and operable to transmit data indicative of one or more of sponge size and the surface area of contact of the sponge with the tissue of the subject.

In addition, Applicants submit that, assuming *arguendo*, every element of the presently pending claims were taught or suggested, a *prima facie* case of obviousness cannot be established since there is no motivation to modify Jacobsen et al. with Sun et al. to provide a sponge having surface area of contact with a tissue. In this regard,

Applicants submit that modifying either of Jacobsen et al. or Sun et al. to provide a sponge with a surface area of contact with a tissue would destroy the principle mode of operation. In particular, Applicants submit that the inability of the device of Jacobson et al. to hold a sponge without the encasing element 82 suggests either that there exists a structural reason or a medical reason why the sponge material 86 of Jacobson et al. should not, or could not, be in direct contact with the tissue. In the alternative, it may be suggested that the sponge used by Jacobson et al. is in fact not a sponge but rather a fluid absorbing material which must be encased, thereby avoiding leakage.

Applicants note that the Examiner seems to take the position that claim 18 includes "intended use" elements that are not being given any patentable weight. However, Applicants politely remind the Examiner that, even if the present claim may be interpreted to recite the intended use of the device, such intended use should still be given patentable weight because the cited references are incapable of functioning as claimed. In particular, Applicants submit that neither Jacobsen et al. nor Sun et al. describe devices with a sponge having surface area of contact with a tissue as neither device is described without some sort of material between the sponge and surface contacting the skin. Furthermore, none of the plethora of sensors disclosed in Jacobson et al (see also Sun, page 9, paragraphs [0087]-[0091]) is stated to detect or indicate *"...sponge size or surface area in contact of the sponge with the tissue of the subject"*. As Sun et al do not describe a sponge having surface area of contact with the tissue, its transmitter cannot be deemed to be *"configured and operable to transmit data signal indicative of one or more of sponge size or surface area of contact of the sponge with the tissue of the subject,"* as claimed.

Although Applicants acknowledge that iontophoretic administration of charged drugs, in general, may be known, as set out in the background of the application, little attention has previously been given to the damage that iontophoresis can inflict on the eye or other sensitive tissues. See the application as originally filed at page 3 lines 24-27. The sponge *as claimed* provides improved safety during an iontophoresis process by indicating the sponge size or surface area of contact of the sponge with the treated tissue. As disclosed, for example, in Figs 2-3 (see element 140) the indication of sponge size or surface area of contact is used to set a safety maximum current during the iontophoretic process. Therefore, since unlike the presently claimed subject matter, the device and sponge of Jacobson et al. and Sun et al. would cause damage to the eye or other sensitive tissue with direct contact to the same, the devices of Jacobsen et al. and Sun et al. are not operable with direct contact to a tissue.

In view of the foregoing, it is submitted that nothing in the cited references, whether taken alone, or together, render the claimed invention obvious within the meaning of 35 USC § 103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

II. At page 4 of the Official Action, claims 23-25 and 30 have been rejected under 35 USC § 103(a) as being unpatentable over Jacobsen et al. in view of Sun et al. in further view of Nicolais et al. (US 5,645,592).

The Examiner asserts that it would have been obvious to have modified the sponge of Jacobsen/Sun by coating it with HEMA-methyl methacrylate copolymer as taught by Nicolais for the purpose of increasing water absorption.

In view of the following these rejections are respectfully traversed.

A brief discussion of the relevant authority on obviousness is set forth in § I above.

In addition, independent claim 18, Jacobsen et al. and Sun et al. are also discussed in detail above. Applicants note that claims 23-25 and 30 each depend, either directly or indirectly from claim 18. As discussed, whether taken alone or in combination, Jacobsen et al. and Sun et al. do not teach or suggest a sponge having surface area of contact with the tissue, a porous structure which is capable of absorbing and holding at least 30% w/w of an aqueous solution without dissolving or disintegrating or a data transmitting module configured and operable to transmit data indicative of one or more of sponge size and the surface area of contact of the sponge with the tissue of the subject, as recited in claim 18. In addition, there is no motivation to modify Jacobsen et al. and Sun et al. for the reasons discussed in § 1 above.

Nicolais et al. do not remedy the deficiencies of Jacobsen et al. and Sun et al. Nicolais merely discloses a hydrogel comprising HEMA-methyl methacrylate copolymer, and cannot be configured by the disclosures of Jacobson et al. nor Sun et al. to provide the presently claimed subject matter. Therefore, Applicants submit that, whether taken alone or together, none of the cited references teach or suggest a sponge having surface area of contact with the tissue, a porous structure which is capable of absorbing and holding at least 30% w/w of an aqueous solution without dissolving or disintegrating or a data transmitting module configured and operable to transmit data indicative of one or more of sponge size and the surface area of contact of the sponge with the tissue of the subject. Accordingly, Applicants submit that the presently claimed subject matter is not obvious.

In view of the foregoing, it is submitted that nothing in the cited references, whether taken alone, or together, render the claimed invention obvious within the meaning of 35 USC § 103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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